



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

SEP 1 1989

MEMORANDUM

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA Reg. No. 1471-101.                      Tebuthiuron.  
Letter of August 9, 1989: Multiresidue Protocol Data.  
DEB#: 5712                      HED#: 9-2014                      MRID#: 411969-00, -01.

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THRU: Robert S. Quick, Section Head  
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TO: J. Edwards, PM Team 74  
Reregistration Branch  
Special Review & Reregistration Division (H7508C)

BACKGROUND

By letter dated 8/9/89, Elanco Products Company, registrant of products containing tebuthiuron as active ingredient, has submitted the following multiresidue test data in accordance with the protocols set forth in the FDA Pesticide Analytical Manual, Volume I, (PAM I), Appendix II:

"Multiresidue Methodology Testing of Tebuthiuron and 6 of its Metabolites", by Paul R. Lear (author), Lilly Research Laboratories, Greenfield IN (sponsor), Sponsor Study No. AAC8913, EPL Bio-Analytical Services, Inc. (performing laboratory), Laboratory Project ID 132-002, 6/30/89, 56 pages.                      MRID# 411969-01.

These data were submitted in response to a data gap listed in the Tebuthiuron Registration Standard (issued 7/87; see Table A - Generic Data Requirements for Tebuthiuron, §158.125 [recodified to §158.240]; footnote 5; page 45), which states:

"Residues of tebuthiuron and metabolites 104, 106, 109, and 103(OH) in or on crop samples must be subjected to analysis by multiresidue protocols."

DISCUSSION

Elanco has submitted a study (MRID# 411969-01) that evaluates the detection of tebuthiuron and 6 of its metabolites (104, 106, 108, 109, 103(OH), and 104(OH)) under the appropriate FDA Multiresidue Methodology (MRM) Testing Protocols.

These compounds have been identified by Elanco, as follows:

<u>CMPD #</u>	<u>DESIGNATION</u>	<u>CHEMICAL NAME</u>
75503	Tebuthiuron	<u>N</u> -[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]- <u>N,N'</u> -dimethylurea
109383	104	<u>N</u> -[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]- <u>N</u> -methylurea
93036	106	<u>N</u> -[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]urea
85372	108	5-(1,1-Dimethylethyl)-1,3,4-thiadiazol-2-amine
83582	109	<u>N</u> -[5-(1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]- <u>N'</u> -hydroxymethyl- <u>N</u> -methylurea
106624	103 (OH)	<u>N</u> -[5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]- <u>N,N'</u> -dimethylurea
124177	104 (OH)	<u>N</u> -[5-(2-hydroxy-1,1-dimethylethyl)-1,3,4-thiadiazol-2-yl]- <u>N</u> -methylurea

To summarize the results, the recovery of tebuthiuron and its 6 metabolites could not be determined by FDA Protocols I and III. FDA Protocols II and IV were not used, based on the MRM Decision Tree.

This study is being forwarded to FDA for evaluation/inclusion in a future updating of PAM I.

#### CONCLUSIONS

Barring a request for additional information from FDA, EPA will consider this study sufficient to fulfill the data requirement for MRM testing of the Tebuthiuron Registration Standard.

cc: M. Nelson, [REDACTED], Circ. (7), Tebuthiuron Reg. Std. File, Tebuthiuron Subject File, M. Bradley, R. Schmitt, ISB/PMSD (E. Eldredge).

H7509C:DEB:Reviewer(MJN):CM#2:Rm804:557-7423:typist(mjn):  
1471TEBU.MRM:8/31/89.

RDI:SecHead:RSQuick:8/31/89:BrSrScientist:RALoranger:8/31/89.